UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ASTRA AKTIEBOLAG, et al., Plaintiffs, -v- ANDRX PHAMACEUTICALs, Inc., Defendant.	99 Civ. 9887 (DLC) OPINION & ORDER

APPEARANCES:

For plaintiffs:

Errol B. Taylor
Fredrick M. Zullow
Suraj K. Balusu
MILBANK, TWEED, HADLEY & McCLOY LLP
1 Chase Manhattan Plaza
New York, NY 10005

For defendant:

Richard F. Lawler
Lori Van Auken
WINSTON & STRAWN LLP
200 Park Ave.
New York, NY 10166

Michael K. Nutter
Peter J. Slawniak
WINSTON & STRAWN LLP
35 West Wacker Dr.
Chicago, IL 60601

Peter E. Perkowski
WINSTON & STRAWN LLP
333 S. Grand Ave., Suite 3800
Los Angeles, CA 90071

Plaintiffs Astra Aktiebolag, Aktiebolaget Hassle, KBI-E, Inc., KBI, Inc., and Astrazeneca LP (collectively, "Astra") filed this action against Andrx Pharmaceuticals, Inc. ("Andrx") in 1999, alleging patent infringement in connection with Andrx's efforts to manufacture and sell a generic form of omeprazole, popularly known by its trade name, Prilosec. Before the Court is Andrx's March 8, 2013, motion for summary judgment. For the following reasons, the motion is denied.

BACKGROUND

A more detailed factual history of this long-running dispute can be found in the Court's prior Opinions and will not be recited here beyond what is necessary to put the current dispute in context. This suit concerns the filing by Andrx and other generic manufacturers of Abbreviated New Drug Applications (or "ANDAs") for generic omeprazole. Several such cases were consolidated before The Hon. Barbara S. Jones,[1] and trial was divided into four phases. The first phase, which dealt with infringement and validity of certain of the patents at issue, began in December 2001. On October 16, 2002, Judge Jones issued

[1] Four remaining cases, including this one, were reassigned to this Court on December 20, 2012.

an Opinion finding, inter alia, that the claims at issue were valid and had been infringed by Andrx. Astra Aktiebolag v. Andrx Pharmaceuticals, Inc., 222 F. Supp. 2d 423 (S.D.N.Y. 2002). On October 30, Judge Jones entered a final judgment, which found in favor of Astra with regard to infringement and enjoined Andrx from manufacturing its omeprazole formulation. Andrx appealed the October 16 Opinion, and the Federal Circuit affirmed. 84 Fed. App'x 76 (Fed. Cir. 2003).

Immediately before the commencement of the trial in 2001, Astra discovered that Andrx had begun manufacturing batches of omeprazole (the "validation batches"). At the time, Andrx's CFO acknowledged on a conference call with investors that the company had produced $41 million "at cost of generic Prilosec," which he speculated could generate "$650 million of net sales." After consulting with the parties, Judge Jones asked Andrx whether it wished to delay the trial so that Astra could be provided with discovery concerning the validation batches. Andrx indicated that it preferred to proceed to trial and have the issue of infringement litigated solely on the basis of its ANDA, and not the omeprazole that had been produced. In July 2007, after the Federal Circuit affirmed another of the District Court's Opinions regarding certain other patents at issue, see In re Omeprazole Patent Litig., 438 F.3d 1364 (Fed. Cir. 2007),

Astra informed Andrx and Judge Jones that it viewed the issue of damages in connection with Andrx's manufacture of the validation batches as outstanding.

On November 21, 2008, Astra filed a motion for leave to file a supplemental complaint alleging additional facts with regard to its claim for damages. Andrx opposed this request, arguing (1) that the final judgment barred the addition of the damages theory, (2) that supplementation would be futile because it would be untimely and because Astra was not legally entitled to damages for Andrx's manufacture of the validation batches, and finally (3) that Astra had unduly delayed in seeking supplementation and that Andrx would be prejudiced by that delay. In an Opinion of February 2, 2010, Judge Jones rejected these arguments and granted Astra's motion, allowing it to add the damages remedy. 695 F. Supp. 2d 21 (S.D.N.Y. 2010). Astra filed its Second Supplemental Complaint on February 8, 2010, and on February 16 Andrx filed a motion for reconsideration of Judge Jones's February 2 Opinion, which she denied in an Order of April 5, 2010.

On March 8, 2013, Andrx filed a motion for summary judgment, which was fully submitted on April 5. Trial in this action is scheduled to begin on September 30.

DISCUSSION

In seeking summary judgment, Andrx makes two principal arguments, both of which were presented to Judge Jones in connection with Andrx's opposition to Astra's motion to supplement its complaint, and neither of which has merit. First, Andrx argues that it is undisputed that it never sold any of the omeprazole it manufactured in 2001 and that, as a matter of statutory interpretation, Astra is therefore not entitled to damages for "commercial manufacture" under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(4)(C). Second, Andrx argues that Judge Jones's entry of a final judgment granting an injunction in 2002 bars Astra from seeking monetary damages. Neither of these arguments entitles Andrx to summary judgment, both because they were already resolved and are therefore barred under the law of the case doctrine and because they lack merit.

Summary judgment may not be granted unless the submissions of the parties taken together "show that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party bears the burden of demonstrating the absence of a dispute as to a material fact, and in making this determination the court must view all facts in the light most favorable to the non-moving party. Anderson v. Liberty Lobby, Inc., 477 U.S.

242, 247 (1986); Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). When the moving party has asserted facts showing that the non-movant's claims cannot be sustained, the opposing party must "set forth specific facts showing that there is a genuine issue for trial," and cannot rest on mere "allegations or denial" of the movant's pleadings. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986); Hicks v. Baines, 593 F.3d 159, 166 (2d Cir. 2010).

Under the law of the case doctrine, "a court should not reopen issues decided in earlier stages of the same litigation." Agostini v. Felton, 521 U.S. 203, 236 (1997). While it is not mandatory, the law of the case doctrine "counsels a court against revisiting its prior rulings in subsequent stages of the same case absent cogent and compelling reasons such as an intervening change of controlling law, the availability of new evidence, or the need to correct a clear error or prevent manifest injustice." Ali v. Mukasey, 529 F.3d 478, 490 (2d Cir. 2008) (citation omitted).

I. Damages for "commercial manufacture"

The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly known as the Hatch-Waxman Act, allows a generic manufacturer of an already approved brand-name drug to obtain expedited approval to

market that drug by filing an ANDA. See F.T.C. v. Actavis, Inc., 133 S. Ct. 2223, 2228 (2013). The filing of an ANDA pursuant to 35 U.S.C. § 355(j)(2)(A)(vii)(IV), as Andrx did in this case, counts as an act of infringement, and allows the generic manufacturer and the brand-name patentee to litigate issues of infringement before the generic is approved. Actavis, 133 S. Ct. at 2228. A generic that is the first to file an ANDA under this subdivision enjoys a period of 180 days of exclusivity from the first commercial marketing of its drug, a period that represents "the vast majority of potential profits for a generic drug manufacturer." Id. at 2229 (citation omitted). The Hatch-Waxman Act provides that, for an infringement action based on the filing of an ANDA, "damages or other monetary relief may be awarded . . . only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug." 35 U.S.C. § 271(e)(4)(C).

Andrx's principal argument in this summary judgment motion is that because it never sold the omeprazole it manufactured in 2001, Astra is barred from receiving damages under § 271(e)(4)(C), since Andrx's mere manufacture, without sale, does not qualify as "commercial manufacture" within the meaning of the statute. Andrx made this very argument, citing several

of the same cases, to Judge Jones in opposing Astra's motion for leave to file a supplemental complaint. In her February 2, 2010 Opinion, Judge Jones addressed and rejected this argument, finding that "commercial manufacture alone suffices" and distinguishing two of the cases on which Andrx again relies in this briefing. 695 F. Supp. 2d at 29. The Court sees no reason to revisit Judge Jones's conclusions on this point.

Even addressing the matter de novo, it is clear that Andrx's argument lacks merit. Andrx suggests that the term "commercial manufacture" in § 271(e)(4)(C) should be read to mean "commercial marketing," a term that is used in the legislative history. See H.R. Rep. No. 98-857, pt. 2, at 24 (Aug. 1, 1984), 1984 U.S.C.C.A.N. 2686, 2711. Andrx does not, however, demonstrate that the statute is ambiguous such that a resort to legislative history is proper, see Connecticut Nat. Bank v. Germain, 503 U.S. 249, 254 (1992), nor does Andrx explain why Congress would use the term "commercial manufacture" when what it really meant was "commercial marketing," a substitution it could well have made itself. Indeed, the statute provides damages for a disjunctive list of activities: "commercial manufacture, use, offer to sell, or sale." 35 U.S.C. § 271(e)(4)(C). Andrx's suggestion that the term "commercial manufacture" requires "marketing" would make the

terms "offer to sell, or sale" redundant, violating a basic canon of statutory interpretation. See Sacirbey v. Guccione, 589 F.3d 52, 66 (2d Cir. 2009). Andrx has, in short, offered no reason to depart from a natural reading of the statutory text, which suggests that a drug can be manufactured commercially even if it is never ultimately sold.

II. "Double Recovery"

Andrx next argues that allowing Astra to pursue damages would be improper "double recovery," since Astra has already obtained a final judgment granting injunctive relief on the same claims. Once again, this argument was made to Judge Jones in 2010. Judge Jones rejected it, observing that the entry of final judgment as to infringement liability did not "preclude the possibility of additional remedies for that infringement." 651 F. Supp. 2d at 26. Andrx has presented no compelling reason why this prior ruling should be revisited. See Ali, 529 F.3d at 490.

Even on the merits, Andrx's argument fails. As an initial matter, the statute provides both injunctive relief and damages as available remedies. 35 U.S.C. § 271(e)(4). Moreover, the final judgment entered in 2002 enjoined Andrx from manufacturing omeprazole until the patents at issue expired. It did not resolve the issue of whether Astra might be entitled to damages

based on prior acts of infringement by Andrx. That Andrx was enjoined from infringing the patents going forward does not render any damages award for past infringement "double recovery." The cases cited by Andrx are inapposite. See, e.g., Forster v. Boss, 97 F.3d 1127, 1128-29 (8th Cir. 1996) (plaintiff not entitled to both forms of relief sought, since either one would make plaintiff whole); Estate of Young v. Williams, 810 F.2d 363, 365 (2d Cir. 1987) (plaintiffs not entitled to bring two separate suits seeking two forms of relief for conduct that occurred before both suits were filed).

CONCLUSION

Andrx's March 8, 2013 motion for summary judgment is denied.

SO ORDERED:

Dated: New York, New York
August 5, 2013

DENISE COTE
United States District Judge